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EXAMINER

SGAGIAS, MAGDALENE K

ART UNIT PAPER NUMBER

1632

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/758,554	Applicant(s) MUMMERY, CHRISTINE LINDSAY	
	Examiner Magdalene K. Sgagias	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 45-132 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 45-132 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Claims 45-132 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

**Linking = 45-55, 59-61, 68-70, 87-91.**

- I. Claims 56-58, 62-64, 66 and 72, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an embryonic stem cell, a pluripotent stem cells or a totipotent stem cell and where the undifferentiated stem cells differentiates into a skeletal muscle cell or cell lineage, classified in class 435, subclass 377.
- II. Claim 56 and 62-64, 66 and 72, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of

undifferentiated stem cells, where the stem cell is a hematopoietic stem cell and where the undifferentiated stem cells differentiates into a skeletal muscle cell or cell lineage, classified in class 435, subclass 377.

- III. Claim 56 and 62-64, 66 and 72, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a mesenchymal stem cell and where the undifferentiated stem cells differentiates into a skeletal muscle cell or cell lineage, classified in class 435, subclass 377.
- IV. Claim 56 and 62-64, 66 and 72, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a neural stem cell and where the undifferentiated stem cells differentiates into a skeletal muscle cell or cell lineage, classified in class 435, subclass 377.

- V. Claim 56 and 62-64, 66 and 72, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an adult stem cell and where the undifferentiated stem cells differentiates into a skeletal muscle cell or cell lineage, classified in class 435, subclass 377.
- VI. Claims 56-58, 62, 63, 65 and 71, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an embryonic stem cell, a pluripotent stem cells or a totipotent stem cell and where the undifferentiated stem cells differentiates into a cardiac muscle cell or cell lineage, classified in class 435, subclass 377.
- VII. Claim 56 and 62, 63, 65 and 71, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell

that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a hematopoietic stem cell and where the undifferentiated stem cells differentiates into a cardiac muscle cell or cell lineage, classified in class 435, subclass 377.

VIII. Claim 56 and 62, 63, 65 and 71, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a mesenchymal stem cell and where the undifferentiated stem cells differentiates into a cardiac muscle cell or cell lineage, classified in class 435, subclass 377.

IX. Claim 56 and 62, 63, 65 and 71, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of

undifferentiated stem cells, where the stem cell is a neural stem cell and where the undifferentiated stem cells differentiates into a cardiac muscle cell or cell lineage, classified in class 435, subclass 377.

- X. Claim 56 and 62, 63, 65 and 71, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an adult stem cell and where the undifferentiated stem cells differentiates into a cardiac muscle cell or cell lineage, classified in class 435, subclass 377.

- XI. Claims 56-58, 62, 63, 67-69 and 73, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an embryonic stem cell, a pluripotent stem cells or a totipotent stem cell and where the undifferentiated stem cells differentiates into a endothelial cell or cell lineage, classified in class 435, subclass 377.

- XII. Claim 56, 62, 63, 67-69 and 73, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a hematopoietic stem cell and where the undifferentiated stem cells differentiates into a endothelial cell or cell lineage, classified in class 435, subclass 377.
- XIII. Claim 56, 62, 63, 67-69 and 73, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a mesenchymal stem cell and where the undifferentiated stem cells differentiates into a endothelial cell or cell lineage, classified in class 435, subclass 377.
- XIV. Claim 56, 62, 63, 67-69 and 73, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell



population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a neural stem cell and where the undifferentiated stem cells differentiates into a endothelial cell or cell lineage, classified in class 435, subclass 377.

- XV. Claim 56, 62, 63, 67-69 and 73, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an adult stem cell and where the undifferentiated stem cells differentiates into a endothelial cell or cell lineage, classified in class 435, subclass 377.

- XVI. Claims 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an embryonic stem cell, a

pluripotent stem cells or a totipotent stem cell and where the undifferentiated stem cells differentiates into a epithelial cell or cell lineage, classified in class 435, subclass 377.

XVII. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a hematopoietic stem cell and where the undifferentiated stem cells differentiates into a epithelial cell or cell lineage, classified in class 435, subclass 377.

XVIII. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a mesenchymal stem cell and where the undifferentiated stem cells differentiates into a epithelial cell or cell lineage, classified in class 435, subclass 377.

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- XIX. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a neural stem cell and where the undifferentiated stem cells differentiates into a epithelial cell or cell lineage, classified in class 435, subclass 377.
- XXI. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an adult stem cell and where the undifferentiated stem cells differentiates into a epithelial cell or cell lineage, classified in class 435, subclass 377.
- XXI. Claims 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell

population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an embryonic stem cell, a pluripotent stem cells or a totipotent stem cell and where the undifferentiated stem cells differentiates into a hematopoietic cell or cell lineage, classified in class 435, subclass 377.

XXII. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a hematopoietic stem cell and where the undifferentiated stem cells differentiates into a hematopoietic cell or cell lineage, classified in class 435, subclass 377.

XXIII. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem

cells, where the stem cell is a mesenchymal stem cell and where the undifferentiated stem cells differentiates into a hematopoietic cell or cell lineage, classified in class 435, subclass 377.

XXIV. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a neural stem cell and where the undifferentiated stem cells differentiates into a hematopoietic cell or cell lineage, classified in class 435, subclass 377.

XXV. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an adult stem cell and where the undifferentiated stem cells differentiates into a hematopoietic cell or cell lineage, classified in class 435, subclass 377.

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- XXVI. Claims 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is an embryonic stem cell, a pluripotent stem cells or a totipotent stem cell and where the undifferentiated stem cells differentiates into a neural cell or cell lineage, classified in class 435, subclass 377.
- XXVII. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a hematopoietic stem cell and where the undifferentiated stem cells differentiates into a neural cell or cell lineage, classified in class 435, subclass 377.
- XXVIII. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the

differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a mesenchymal stem cell and where the undifferentiated stem cells differentiates into a neural cell or cell lineage, classified in class 435, subclass 377.

XXIX. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem cells, where the stem cell is a neural stem cell and where the undifferentiated stem cells differentiates into a neural cell or cell lineage, classified in class 435, subclass 377.

XXX. Claim 56 and 62, drawn to a method of causing non-spontaneous and controlled differentiation of an undifferentiated stem cell into a mesodermal cell comprising applying a differentiation signal to the undifferentiated stem cell that induces the differentiation of the stem cell and a method of obtaining a cell population comprising a sub-population of differentiated cells of a mesodermal lineage wherein the differentiated cells are derived from undifferentiated stem cells in the cell population comprising causing the differentiation of undifferentiated stem

cells, where the stem cell is an adult stem cell and where the undifferentiated stem cells differentiates into a neural cell or cell lineage, classified in class 435, subclass 377.

**Linking = 74-76, 86-88.**

XXXI. Claims 77, 78, 79, 81 and 83-85 drawn to an isolated cell population comprising a sub-population of skeletal muscle cells of a cell lineage where the differentiated cells are derived from undifferentiated ES cells, pluripotent stem cells or totipotent stem cells within the cell population, classified in class 435, subclass 325.

XXXII. Claims 77, 78, 79, 80, 81, 83-85, 89 and 128-132, drawn to an isolated cell population comprising a sub-population of cardiomyocytes of a cell lineage where the differentiated cells are derived from undifferentiated ES cells, pluripotent stem cells or totipotent stem cells within the cell population and a cardiomyocyte, classified in class 435, subclass 325.

XXXIII. Claims 77, 78 and 82-85, drawn to an isolated cell population comprising a sub-population of endothelial cells of a cell lineage where the differentiated cells are derived from undifferentiated ES cells, pluripotent stem cells or totipotent stem cells within the cell population, classified in class 435, subclass 325.

XXXIV. Claim 77 and 83-85, drawn to an isolated cell population comprising a sub-population of epithelial cells of a cell lineage where the differentiated cells are derived from undifferentiated ES cells, pluripotent stem cells or totipotent stem cells within the cell population, classified in class 435, subclass 325.

XXXV. Claims 77 and 83-85, drawn to an isolated cell population comprising a sub-population of hematopoietic cells of a cell lineage where the differentiated cells



are derived from undifferentiated ES cells, pluripotent stem cells or totipotent stem cells within the cell population, classified in class 435, subclass 325.

XXXVI. Claims 77 and 83-85, drawn to an isolated cell population comprising a sub-population of neural cells of a cell lineage where the differentiated cells are derived from undifferentiated ES cells, pluripotent stem cells or totipotent stem cells within the cell population, classified in class 435, subclass 325.

XXXVII. Claims 77, 78, 79, 81 and 83, drawn to an isolated cell population comprising a sub-population of skeletal muscle cells of a cell lineage where the differentiated cells are derived from undifferentiated hematopoietic stem cells within the cell population, classified in class 435, subclass 325.

XXXVIII. Claims 77, 78, 79, 80, 83, 89, 128-130 and 132, drawn to an isolated cell population comprising a sub-population of cardiomyocytes of a cell lineage where the differentiated cells are derived from undifferentiated hematopoietic stem cells within the cell population and a cardiomyocyte, classified in class 435, subclass 325.

XXXIX. Claims 77, 78, 82 and 83, drawn to an isolated cell population comprising a sub-population of endothelial cells of a cell lineage where the differentiated cells are derived from undifferentiated hematopoietic stem cells within the cell population, classified in class 435, subclass 325.

XL. Claim 77 and 83, drawn to an isolated cell population comprising a sub-population of epithelial cells of a cell lineage where the differentiated cells are derived from undifferentiated hematopoietic stem cells within the cell population, classified in class 435, subclass 325.

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- XLII. Claims 77 and 83, drawn to an isolated cell population comprising a sub-population of hematopoietic cells of a cell lineage where the differentiated cells are derived from undifferentiated hematopoietic stem cells within the cell population, classified in class 435, subclass 325.
- XLIII. Claims 77 and 83, drawn to an isolated cell population comprising a sub-population of neural cells of a cell lineage where the differentiated cells are derived from undifferentiated hematopoietic stem cells within the cell population, classified in class 435, subclass 325.
- XLIV. Claims 77, 78, 79, 81 and 83, drawn to an isolated cell population comprising a sub-population of skeletal muscle cells of a cell lineage where the differentiated cells are derived from undifferentiated mesenchymal stem cells within the cell population, classified in class 435, subclass 325.
- XLV. Claims 77, 78, 79, 80, 83, 89, 128-130 and 132, drawn to an isolated cell population comprising a sub-population of cardiomyocyte of a cell lineage where the differentiated cells are derived from undifferentiated mesenchymal stem cells within the cell population and a cardiomyocyte, classified in class 435, subclass 325.
- XLVI. Claims 77, 78, 82 and 83, drawn to an isolated cell population comprising a sub-population of endothelial cells of a cell lineage where the differentiated cells are derived from undifferentiated mesenchymal stem cells within the cell population, classified in class 435, subclass 325.
- XLVII. Claim 77 and 83, drawn to an isolated cell population comprising a sub-population of epithelial cells of a cell lineage where the differentiated cells are

derived from undifferentiated mesenchymal stem cells within the cell population, classified in class 435, subclass 325.

XLVII. Claims 77 and 83, drawn to an isolated cell population comprising a sub-population of hematopoietic cells of a cell lineage where the differentiated cells are derived from undifferentiated mesenchymal stem cells within the cell population, classified in class 435, subclass 325.

XLVIII. Claims 77 and 83, drawn to an isolated cell population comprising a sub-population of neural cells of a cell lineage where the differentiated cells are derived from undifferentiated mesenchymal stem cells within the cell population, classified in class 435, subclass 325.

XLIX. Claims 77, 78, 79, 81 and 83, drawn to an isolated cell population comprising a sub-population of skeletal muscle cells of a cell lineage where the differentiated cells are derived from undifferentiated neural stem cells within the cell population, classified in class 435, subclass 325

L. Claims 77, 78, 79, 80, 83, 89, 128-130 and 132, drawn to an isolated cell population comprising a sub-population of cardiomyocytes of a cell lineage where the differentiated cells are derived from undifferentiated neural stem cells within the cell population and a cardiomyocyte, classified in class 435, subclass 325

LI. Claims 77, 78, 82 and 83, drawn to an isolated cell population comprising a sub-population of endothelial cells of a cell lineage where the differentiated cells are derived from undifferentiated neural stem cells within the cell population, classified in class 435, subclass 325.

LII. Claim 77 and 83, drawn to an isolated cell population comprising a sub-population of epithelial cells of a cell lineage where the differentiated cells are

derived from undifferentiated neural stem cells within the cell population, classified in class 435, subclass 325.

- LIII. Claims 77 and 83, drawn to an isolated cell population comprising a sub-population of hematopoietic cells of a cell lineage where the differentiated cells are derived from undifferentiated neural stem cells within the cell population, classified in class 435, subclass 325.
- LIV. Claims 77 and 83, drawn to an isolated cell population comprising a sub-population of neural cells of a cell lineage where the differentiated cells are derived from undifferentiated neural stem cells within the cell population, classified in class 435, subclass 325.
- LV. Claims 77, 78, 79, 81 and 83, drawn to an isolated cell population comprising a sub-population of skeletal muscle cells of a cell lineage where the differentiated cells are derived from undifferentiated adult stem cells within the cell population, classified in class 435, subclass 325.
- LVI. Claims 77, 78, 79, 80, 83, 89, 128-130 and 132, drawn to an isolated cell population comprising a sub-population of cardiomyocytes of a cell lineage where the differentiated cells are derived from undifferentiated adult stem cells within the cell population and a cardiomyocyte, classified in class 435, subclass 325.
- LVII. Claims 77, 78, 82 and 83, drawn to an isolated cell population comprising a sub-population of endothelial cells of a cell lineage where the differentiated cells are derived from undifferentiated adult stem cells within the cell population, classified in class 435, subclass 325.
- LVIII. Claim 77 and 83, drawn to an isolated cell population comprising a sub-population of epithelial cells of a cell lineage where the differentiated cells are

derived from undifferentiated adult stem cells within the cell population, classified in class 435, subclass 325.

- LIX. Claims 77 and 83, drawn to an isolated cell population comprising a sub-population of hematopoietic cells of a cell lineage where the differentiated cells are derived from undifferentiated adult stem cells within the cell population, classified in class 435, subclass 325.
- LX. Claims 77 and 83, drawn to an isolated cell population comprising a sub-population of neural cells of a cell lineage where the differentiated cells are derived from undifferentiated adult stem cells within the cell population, classified in class 435, subclass 325.
- LXI. Claims 92-101, drawn to an isolated factor that causes specific differentiation of a stem cell, classified in class 530, subclass 350.
- LXII. Claims 102-108, drawn to a method of causing differentiation of a stem cells to cell lineage by exposure to an isolated factor, classified in class 435, subclass 377.
- LXIII. Claims 109-116, drawn to a method of treating or preventing cardiac disease, classified in class 424, subclass 93.2.
- LXIV. Claims 117-120, drawn to a method of treating or preventing muscle disease, classified in class 424, subclass 93.2.
- LXV. Claims 121-124, drawn to a method of treating or preventing a vascular disease, classified in class 424, subclass 93.2.
- LXVI. Claims 125-128, drawn to a model for testing suitability of a cardiomyocytes cell for cardiac transplantation, classified in class 800, subclass 9.
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Claims 45-55, 59-61, 68-70, 87-91 links inventions I-XXX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 45-55, 59-61, 68-70, 87-91. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I-XXX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are of different modes of operation. For example, invention I is to a method of causing non-spontaneous and controlled differentiation of an undifferentiating stem cell into a skeletal muscle cell or cell lineage, where the stem cell is an embryonic stem cell. Invention II is to a method of causing non-spontaneous and controlled differentiation of an undifferentiating stem cell into a skeletal muscle cell or cell lineage, where the stem cell is a hematopoietic stem cell. The protocol for causing non-spontaneous and controlled differentiation of an undifferentiating stem cell into a skeletal muscle cell or cell lineage from a an embryonic stem cell is materially different and separate from a hematopoietic stem cell.

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Claims 74-76, 86-88 links inventions XXXI-LXVI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 74-76, 86-88.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions XXXI-LXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are of different modes of operation. Invention XXXI is to a sub-population of skeletal muscle cells of a cell lineage. Invention XXXII is to a sub-population of cardiomyocytes of a cell lineage. The sub-population of skeletal muscle cells of a cell lineage operate under the correct conditions derived for skeletal muscle cells. The sub-population of cardiomyocytes of a cell lineage of invention XXXII operate by developing under the correct conditions of cardiomyocytes. Thus, each cells of inventions XXXI-LXI is patentably distinct because they have materially distinct and separate physiologic functions.

Inventions LXII-LXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of

operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are of different modes of operation. The invention of the groups LXII-LXVI are distinct from each other because they are drawn to methods that have distinct steps, require separate compositions for practice and produce different results. For example, invention LXII is to a method of causing differentiation of a stem cell to a cell lineage by exposure to an isolated factor. Invention LXIII is to a method of treating or preventing cardiac disease. Inventions LXII and LXIII require materially different and separate protocols.

Inventions XXXI-LXI and LXII-LXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are of different modes of operation. The compositions of the groups XXXI-LXI are patentably distinct each from the methods of the groups LXII-LXVI because these methods cannot be used in the methods or will be used in more than one method.

Therefore, the inventions of the groups I-LXVI are patentably distinct each from the other and will require separate and non-coextensive searches in the patent and non-patent literature.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their recognized divergent subject matter, separate classification and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.



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The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and the fee required under 37 C.F.R. 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla, can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.  
Art Unit 1632

  
**DEBORAH CROUCH**  
**PRIMARY EXAMINER**  
**GROUP 1800**